JC06 Rec'd PCT/PTO 0 9 MAY 2005

Clean Version of Amended Claims

- 1 (Original). A method for the identification and/or quantification of endothelial cells being related to cardiovascular diseases in a sample, wherein the method comprises the following steps:
- (a) obtaining a sample to be analyzed containing endothelial cells;
- (b) incubating the sample with one or several molecules that specifically bind to one or several of the following marker molecules of the endothelial cells:
- endothelial cell-markers and/or markers for apoptosis, or
- endothelial cell-markers and/or markers of endothelial precursor cells;
- (c) identification and/or quantification of the endothelial cells on the basis of the bound molecules by using immunocytological methods; and
- (d) comparing the result obtained for the sample to be analyzed with the result of a reference sample.
- 2 (Currently amended). The method according to claim 1, wherein said endothelial cells are derived from a mammal.
- 3 (Currently amended). The method according to claim 1, wherein said endothelial cells are selected from the group consisting of apoptotic endothelial cells, endothelial precursor cells, and mature endothelial cells.
- 4 (Currently amended). The method according to claim 1, wherein said sample to be analyzed is selected from the group consisting of peripheral blood, cell culture-suspensions and suspensions containing cells that have been released mechanically, chemically and/or enzymatically from the wall of a vessel.
- 5 (Currently amended). The method according to claim 4, wherein said sample to be analyzed is peripheral blood.
- 6 (Currently amended). The method according to claim 5, wherein a coagulation inhibitor is added to the peripheral blood.

- 7 (Currently amended). The method according to claim 1, wherein said marker-binding molecules are selected from the group consisting of antibodies or parts or fragments thereof, and receptor ligands or parts thereof.
- 8 (Currently amended). The method according to claim 7, wherein said antibodies or parts or fragments thereof comprise polyclonal antibodies, monoclonal antibodies, Fabfragments, scFv-fragments, and diabodies.
- 9 (Currently amended). The method according to claim 1, wherein said marker-binding molecules are present in solution or matrix-immobilized.
- 10 (Currently amended). The method according to claim 1, wherein said marker-binding molecules are coupled to one or several detection molecules from the group consisting of fluorescein thioisocyanate, phycoerythrine, enzymes, and magnetic beads.
- 11 (Currently amended). The method according to claim 1, wherein said marker-binding molecules are detected with an antibody being coupled to one or several detection molecules.
- 12 (Currently amended). The method according to claim 1, wherein said endothelial cellular marker is selected from the group consisting of CD146, von Willebrandt-factor (vWF), and vascular endothelial growth factor-receptor 1 (VEGF-receptor-1).
- 13 (Currently amended). The method according to claim 1, wherein said marker for apoptosis is selected from the group consisting of annexin V[[,]] and PD-ECGF.
- 14 (Currently amended). The method according to claim 1, wherein said markers of endothelial precursor cells are selected from the group consisting of CD133 and CD34.
- 15 (Currently amended). The method according to claim 1, wherein furthermore at least one marker being characteristic for non-endothelial cells is determined.

- 16 (Currently amended). The method according to claim 1, wherein said immunocytological methods are selected from the group consisting of flow cytometry and solid-phase-immunoassays.
- 17 (Currently amended). The method according to claim 1, wherein said reference sample is derived from a mammal, wherein a cardiovascular disease was excluded.
- 18 (Currently amended). The method according to claim 1, wherein said result for apoptotic endothelial cells is brought in relation with the result for the totality of endothelial cells.
- 19 (Currently amended). The method according to claim 1, wherein said result for apoptotic endothelial cells is brought in relation with the result for the endothelial cells.
- 20 (Currently amended). The method according to claim 1, further comprising a lysis of the erythrocytes between step (a) and (b).
- 21 (Currently amended). The method according to claim 1, wherein said cardiovascular diseases are selected from the group consisting of stable and unstable angina, myocardial infarction, acute cardiac syndrome, coronary arterial disease and heart insufficiency.
- 22 (Currently amended). A diagnostic kit, comprising means for performing a method for the identification and/or quantification of endothelial cells being related to cardiovascular diseases in a sample, wherein the method comprises the following steps:
- (a) obtaining a sample to be analyzed containing endothelial cells;
- (b) incubating the sample with one or several molecules that specifically bind to one or several of the following marker molecules of the endothelial cells:
- endothelial cell-markers and/or markers for apoptosis, or
- endothelial cell-markers and/or markers of endothelial precursor cells;
- (c) identification and/or quantification of the endothelial cells on the basis of the bound molecules by using immunocytological methods; and
- (d) comparing the result obtained for the sample to be analyzed with the result of a reference sample,

optionally together with additional components and/or excipients.

- 23 (Original). A method for the diagnosis and/or prognosis of cardiovascular diseases and/or for the monitoring of their therapy, wherein said method comprises the following steps:
- (a) obtaining a sample to be analyzed containing endothelial cells;
- (b) incubating the sample with one or several molecules that specifically bind to one or several of the following marker molecules of the endothelial cells:
- endothelial cell-markers and/or markers for apoptosis, or
- endothelial cell-markers and/or markers of endothelial precursor cells;
- (c) identification and/or quantification of the endothelial cells on the basis of the bound molecules by using immunocytological methods; and
- (d) comparing the result obtained for the sample to be analyzed with the result of a reference sample.
- 24 (Currently amended). The method according to claim 23, wherein said therapy comprises the administration of lipid lowering substances, selected from the group consisting of statines, in particular atorvastatin.
- 25 (New). The method, according to claim 2, wherein said endothelial cells are derived from a human.
 - 26 (New). The method, according to claim 6, wherein said inhibitor is heparin.